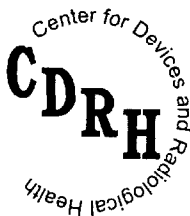


Compliance Guidance

The Mammography Quality Standards Act Final Regulations Document #3

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**U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Inspection Support Branch
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs**

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Charles Finder, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Charles Finder at 301-594-3332.

Additional Copies

World Wide Web/CDRH home page at <http://www.fda.gov/cdrh/mammography> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number (1496) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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Compliance Guidance¹

The Mammography Quality Standards Act

Final Regulations Document #3

Background

The Mammography Quality Standards Act (MQSA) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565).

The FDA is using a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing informational materials to the public. The currently available documents include a quarterly newsletter *Mammography Matters* and an Internet home page (<http://www.fda.gov/cdrh/mammography>) containing all previously issued guidance, including the latest edition of “*Preparing for the MQSA Inspection*.”

¹ This document is intended to provide guidance. It represents the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.

Inspections - General

Question: Our facility has several patient waiting areas. Can I photocopy our facility certificate and place copies in each area?

Answer: While the Statute requires that the original certificate be prominently displayed, the photocopying of the certificate so that it may be displayed in additional areas is not prohibited. However, we recommend that facilities wishing to display their MQSA certificate in several different areas obtain additional certificates (at no charge) by contacting FDA at 1-800-838-7715 or writing to: FDA MQSA Program, P.O. Box 6057, Columbia, MD 21045-6057. Facilities with State-issued MQSA certificates should check with their State agencies for their policies regarding additional certificates. Facilities are reminded that, at a minimum, they must have the original certificate displayed even if they choose to display additional copies of the certificate. Mobile facilities must have at least one original certificate displayed whenever the mobile unit is performing mammography.

Question: We have a mammography unit that is used solely for interventional mammographic procedures. The unit is not MQSA certified. During the course of these interventional procedures, we take mammographic images. Because our unit is not MQSA certified, what restrictions exist on the mammographic images we may perform during such procedures?

Answer: Because interventional mammography is currently excluded from regulation, units that are used solely for interventional procedures do not have to be MQSA certified. However, these uncertified units must not be used to perform conventional mammographic examinations. Uncertified units may be used to produce mammographic images only if they meet all of the following conditions:

1. The mammographic images obtained are an integral part of an interventional procedure.
2. Facilities must not bill separately for these mammographic images. They must bill only for the interventional procedure.
3. If the mammographic images obtained as part of the interventional procedure result in the cancellation of the procedure (e.g. lesion or calcifications no longer seen, calcifications are determined to be in the skin), the facility must not report nor bill the attempted procedure as a mammogram, but rather as a canceled procedure.
4. If the procedure is canceled for reasons described in 3, FDA strongly recommends that the findings (or absence of findings) be confirmed by an immediate follow-up study performed on an MQSA certified unit.

Question: Our facility is currently undergoing accreditation. We meet all MQSA regulatory requirements. However, our accreditation body recommends certain actions that are more stringent than those in the regulations. If we follow MQSA regulations (but do not meet all those recommended by the accreditation body), can our facility be denied accreditation?

Answer: No. If a facility meets all MQSA regulations, its accreditation (or reaccreditation) cannot be denied for failure to meet accreditation body recommendations beyond MQSA requirements. Similarly, additional test(s) not listed in the final regulations cannot be mandated as a condition for a

facility's accreditation or reaccreditation. Facilities are reminded that States have the authority to require more stringent standards than MQSA and that they can enforce these more stringent standards under State laws and regulations (to the point of prohibiting an MQSA certified facility from operating in the State).

Definitions

21 CFR 900.2

(o) Direct supervision means that:

(1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

(2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

Question: Physician A is under the direct supervision of physician B who works at another facility. Physician B provides a letter documenting the number of examinations for which he/she provided direct supervision. Must physician B also include documentation showing that he/she is a qualified interpreting physician?

Answer: No. While physician B must be a qualified interpreting physician, he/she does not have to include documentation showing that he/she is a qualified interpreting physician.

Question: Technologist A is under the direct supervision of technologist B who works at another facility. Technologist B provides a letter documenting the number of examinations for which he/she provided direct supervision. Must technologist B also include documentation showing that he/she is a qualified radiologic technologist?

Answer: No. While technologist B must be a qualified radiologic technologist, he/she does not have to include documentation showing that he/she is a qualified radiologic technologist.

Question: Physicist A is under the direct supervision of physicist B who works at another facility. Physicist B provides a letter documenting the number of surveys for which he/she provided direct supervision. Must physicist B also include documentation showing that he/she is a qualified medical physicist?

Answer: No. While physicist B must be a qualified medical physicist, he/she does not have to include documentation showing that he/she is a qualified medical physicist.

Question: Can direct supervision of an interpreting physician be provided exclusively through the use of telemammography?

Answer: No. At the present time, teleradiology systems have not been approved for primary interpretation of mammograms. Because of this, direct supervision of an interpreting physician cannot be provided exclusively through the use of telemammography. This issue will be revisited when soft copy interpretation of full-field digital mammography or teleradiology systems specifically designed for mammography are approved for clinical use.

21 CFR 900.2(II)

Physical science means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

Question: Is a degree in nuclear physics considered a physical science degree?

Answer: Yes. Nuclear physics is a specialty of physics and therefore meets the physical science degree requirement.

Personnel - General

21 CFR 900.12(a)

Personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

Question: At the time of the inspection, the sole interpreting physician, radiologic technologist, and/or medical physicist at a facility is found to not meet one of their requirements. Must the person and the facility immediately stop practicing mammography?

Answer: If personnel fail to meet a requirement, the facility will be cited. The actions that the facility and the persons involved must or should take will be dependent on the specific circumstances that exist at the facility. For example, if the radiologic technologist fails to meet a requirement, the technologist can continue to perform mammography under the direct supervision of the interpreting physician (as long as the physician meets the technologist qualifications). If the physician fails to meet a requirement, he/she must stop interpreting mammograms independently; however, the facility can continue to perform mammography with the studies being interpreted by a different interpreting physician at a later time. Under no circumstance can the interval between performing and providing the results of the examination exceed 30 days. If the medical physicist fails a requirement, the facility will be cited but can continue to perform and interpret mammograms.

Because the consequences of having a facility cease performing mammography services, even for a short time, can be so detrimental to patient access and patient care, the inspector must take special actions in such cases. If both the interpreting physician and radiologic technologist fail to meet their requirements or other conditions exist that would cause shut down of the facility's operations, the inspector should immediately contact the FDA Inspector Helpdesk for further instructions. In those cases where FDA determines that there is not an immediate risk to human health, the facility can

continue to use the personnel for a limited time so that the problem(s) can be corrected without adversely affecting patient care.

Question: Can time spent directly supervising other personnel, or being directly supervised, count toward the continuing education requirement?

Answer: No. While time spent being directly supervised can be counted toward meeting appropriate initial requirements, time spent directly supervising other personnel or being directly supervised cannot count toward the continuing education requirement for either the supervisor or those being supervised.

Question: Can an interpreting physician position patients or perform mammographic examinations?

Answer: As long as the interpreting physician meets the **qualifications of a radiologic technologist** or is under the direct supervision of a qualified radiologic technologist, he/she can position patients or perform mammographic examinations.

Question: If the person providing direct supervision is found to be unqualified, how does that affect the status of the person being supervised?

Answer: Due to the large number of variables that may be involved, the status of the person being supervised will be determined on a case-by-case basis at the time such situations arise.

Question: If a facility fails to have proper documentation for a personnel requirement, will the facility be cited for failure of the inspection question, "Required personnel documents available?"

Answer: Yes. If the facility is unable to supply the inspector with all the appropriate documentation for any personnel qualifications during the time the inspector is at the facility, the inspector will answer the personnel question, "Required documents available?" with an "N" thereby generating a level 3 finding. Examples include: personnel who do not have any documentation showing they meet any one of their respective personnel requirements, personnel whose documents are not available at the facility but are claiming that they exist, and personnel who have incomplete documentation or whose documentation has been rejected by the inspector.

Interpreting Physician

21 CFR 900.12(a)(1)(ii)(A)

Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

Question: Under the interim regulations, physicians could not count **interventional** mammographic examinations toward the initial or continuing experience requirements. Does this continue under the final regulations?

Answer: Yes. Because interventional mammography is currently excluded from MQSA regulations, performance of interventional mammographic examinations cannot count toward the initial or continuing experience requirements.

Question: If an interpreting physician is the sole owner of a mammography facility (and therefore is considered the most responsible official of the facility), can the interpreting physician document his/her own continuing experience?

Answer: Yes. While acting in the capacity of the most responsible official of the mammography facility, an interpreting physician can document his/her own continuing experience. While such documentation will be accepted in routine cases, it is assumed that this documentation is based upon more extensive records, such as facility logs or reports, and that these could be examined if need be.

Radiologic Technologist

21 CFR 900.12(a)(2)

Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(i) General requirements. (A) Be licensed to perform general radiographic procedures in a State; or

(B) Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and

Question: Does the American Registry of Radiologic Technologists (ARRT) certificate or ARRT(M) certificate have to be stamped with the date it was originally issued?

Answer: The certificate does not have to be stamped with the date it was originally issued. If a technologist is using the ARRT certificate to document general certification, the date of issuance is necessary to establish the technologist's starting date. Therefore, the facility must have some form of documentation identifying this date.

21 CFR 900.12(a)(2)(ii)

Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy, physiology, positioning, compression, quality assurance/quality control techniques, imaging of patients with breast implants;

- (B) *The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and*
- (C) *At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams;*

Question: Can simulated examinations (person not irradiated) count toward the initial, or continuing, or requalification experience requirement?

Answer: No. Simulated examinations are not acceptable toward meeting the experience requirements. While simulations may be useful, the full experience benefit cannot be achieved without the ability to evaluate and learn from the films obtained during an actual examination.

21 CFR 900.12(a)(2)(iv)(A)

Continuing experience requirements. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

Question: Can simulated examinations (person not irradiated) count toward the initial, or continuing, or requalification experience requirement?

Answer: No. Simulated examinations are not acceptable toward meeting the experience requirements. While simulations may be useful, the full experience benefit cannot be achieved without the ability to evaluate and learn from the films obtained during an actual examination.

Question: Under the interim regulations, physicians could not count **interventional** mammographic examinations toward the initial or continuing experience requirements. Has this same policy been extended to radiologic technologists under the final regulations?

Answer: Yes. Because interventional mammography is currently excluded from MQSA regulations, performance of interventional mammographic examinations cannot count toward the initial or continuing experience requirements.

Medical Physicist

21 CFR 900.12(a)(3)

All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:

21 CFR 900.12(a)(3)(i)

Initial Qualifications

- (A) *Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and*
- (B) (1) *Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;*
- (2) *Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and*
- (3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section;*

Question: Is a master's degree in Radiologic Technology sufficient to meet the degree requirement?

Answer: Yes, Radiologic Technology is considered to be a discipline under radiation science and, as such, satisfies the Agency's definition of physical science.

Question: I have a degree in a physical science (see **physical science**) obtained at a non-US institution. Is that acceptable toward meeting the requirement?

Answer: A degree from a non-US institution is acceptable if the physicist can provide information showing that his or her foreign degree is accepted by an accredited US institution, the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by one of the professional certifying bodies approved by FDA. In cases where acceptance of a foreign degree by either an accredited US institution or by one of the FDA-approved professional certifying bodies can not be provided, FDA will evaluate such degrees on a case-by-case basis.

21 CFR 900.12(a)(3)(ii) Alternative Initial Qualifications

- (A) *Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and*
- (B) *Prior to the April 28, 1999, have:*
 - (1) *A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,*
 - (2) *Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and*
 - (3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.*

Question: Is a bachelor's degree in Radiologic Technology sufficient to meet the degree requirement?

Answer: Yes, Radiologic Technology is considered to be a discipline under radiation science and, as such, satisfies the Agency's definition of physical science.

Question: I have a degree in a physical science (see **physical science**) obtained at a non-US institution. Is that acceptable toward meeting the degree requirement?

Answer: A degree from a non-US institution is acceptable if the physicist can provide information showing that his or her foreign degree is accepted by an accredited US institution, the Committee on Accreditation of Medical Physicists Education Programs (CAMPEP), World Education Testing, or by one of the professional certifying bodies approved by FDA. In cases where acceptance of a foreign degree by either an accredited US institution or by one of the FDA-approved professional certifying bodies can not be provided, FDA will evaluate such degrees on a case-by-case basis.

21 CFR 900.12(a)(3)(iii)(B)

Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period on a specific unit within a period of 60 days can be counted towards this requirement.

Question: Under the interim regulations, physicians could not count **interventional** mammographic examinations toward the initial or continuing experience requirements. Will this same policy be extended to medical physicists under the final regulations?

Answer: Yes. Because interventional mammography is currently excluded from MQSA regulations, surveys of interventional mammographic facilities or units can not count toward the initial or continuing experience requirements.

Question: If a medical physicist is the sole owner of a physics consulting business (and therefore is considered the most responsible official of that business), can the medical physicist document his/her own continuing experience?

Answer: Yes. While acting in the capacity of the most responsible official of the physics consulting business, a medical physicist can document his/her own continuing experience. While such documentation will be accepted in routine cases, it is assumed that this documentation is based upon the survey reports and that these could be examined if need be.

Equipment - General

Question: At the time of the inspection, a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service?

Answer: No. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients.

Equipment

21 CFR 900.12(b)(8)(i)

Application of compression. Effective October 28, 2002, each system shall provide: (A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and (B) Fine adjustment compression controls operable from both sides of the patient.

Question: With machines such as the GE 500T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement?

Answer: FDA is in the process of developing proposed guidance regarding this issue based on the public comments it has received. A proposed answer to the above question is scheduled to be issued in Draft Compliance Guidance Document #4.

21 CFR 900.12(b)(8)(ii)

Compression paddle. (A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for ``spot compression'') may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

Question: Can a single paddle meet the requirement of being matched to all full-field image receptors provided for the system?

Answer: No. Section 900.12(b)(8)(ii)(A) specifies that the system must have different paddles matched to each image receptor size provided.

21 CFR 900.12(b)(8)(ii)(B)

Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

21 CFR 900.12(b)(8)(ii)(C)

Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

Question: What documentation should facilities have to show that their mammography compression paddles were designed to not be “flat and parallel to the breast support table?”

Answer: Acceptable documentation would include letters from the manufacturer, copies of manuals provided by the manufacturer, user instructions, or similar manufacturer-provided materials that indicate the design intent of the paddle.

21 CFR 900.12(b)(8)(ii)(D)

The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

Question: One of our compression paddles is not perfectly straight. Does it still meet the requirement?

Answer: The intent of this regulation is to prevent the use of paddles with a significant concave shape to the central portion of the chest wall edge of the paddle. These types of paddles have been found to provide inadequate imaging of chest wall breast tissue.

The edge of the straight paddle does not have to be perfectly straight, but rather, it is required that the manufacturer intended it to be straight and that it be made as straight as manufacturing processes allow. For example, if an original or third party manufacturer offers a paddle with a curved chest wall edge in addition to their straight edge paddle, then the curved paddle would not meet the requirement. As an aid in determining the adequacy of a particular design, the user may consult the manufacturer.

For each x-ray unit, the facility must have at least one standard full-sized compression paddle for both required image receptor sizes. These paddles must have a straight chest wall edge. Special purpose paddles may be provided as needed. Under the regulations, compression paddles that are designed for special purposes are exempt from the requirement that the chest wall edge of the paddle be straight and parallel to the edge of the image receptor. Special purpose paddles are those not routinely used to produce the standard MLO and CC mammographic views.

21 CFR 900.12(b)(9)

Technique factor selection and display. (i) Manual selection of milliampere seconds (mA's) or at least one of its component parts (milliampere (mA) and/or time) shall be available.

(ii) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mA's) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mA's used during the exposure. The mA's may be displayed as mA and time.

Question: If only the preset kVp is displayed by the unit when used in the AEC mode, is it necessary for a "preset" indication of mA and/or mAs to be indicated prior to the exposure?

Answer: Any technique factor that is set prior to exposure in the AEC mode must be indicated. However, the indication need not be by digital display or dial. With units where the kVp is the only factor under direct control of the operator, the corresponding preset mA or mAs may be set automatically by the unit and may not be normally visible on the control panel. However, these corresponding values should be available from the manufacturer, if standard for the model, or from the installer, if they can be set to meet the needs of the facility. If these values are given on a label attached to the control panel or on the technique chart, the unit will be in compliance with this requirement.

21 CFR 900.12(b)(10)

Automatic exposure control. (i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

Question: Do all possible positions of the AEC detector have to be indicated on the compression paddle?

Answer: The intent of this regulation is that the operator be aware of the characteristics of the AEC detector in order to aid in improving image quality. Under some AEC detector designs it may be difficult to meet the requirement. Some detectors cover the entire area of the image receptor and once the exposure begins, they automatically select the region of maximum density as the active area. For such systems, indication of the entire potential active area, along with appropriate instructions in the users manual, would satisfy the requirement. Since the area is automatically selected, the display of the size of the detector is not required. Other designs may have an essentially infinite number of locations under all or part of the image receptor. An indication of the complete range and detector size, coupled with adequate instructions, would be sufficient. Still others may indicate the range of multiple positions on the paddle. Again, this would satisfy the requirement. There may be other methods employed that also satisfy the requirement. The key is that the operators know what areas they may select and the size of the detector.

Question: The position of the AEC detector is infinitely variable over the entire area of the image receptor. How can the position of such a detector be identified on the compression paddle?

Answer: An indication of the range of coverage and the detector size, coupled with instructions on the correct use in the users manual, would satisfy the regulations.

Question: Do paddles designed to be smaller than the full size of the image receptor have to have the AEC detector position identified?

Answer: No. It was not the intent that paddles designed to be smaller than the full size of the image receptor bear the indication. Fenestrated paddles such as those used for invasive procedures are not covered by the regulations.

21 CFR 900.12(b)

- (14) *The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.*
- (15) *Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.*

Question: Do masking view-scopes meet the masking requirement, even if their field of view is smaller than that of the size of the film?

Answer: The requirement is met as long as the masking view-scope can limit the illuminated area to a region equal to or smaller than the exposed portion of the film. If the field of view of the masking view-scope is significantly smaller than the area of visualized breast tissue we recommend that the facility have additional means of masking to allow the interpreting physician the ability to view and compare both breasts at the same time.

Medical Records

21 CFR 900.12(c)(1)

Medical records and mammography reports--(1) Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

Question: Our interpreting physicians send out reports and lay summaries under their own letterhead. Must the certified facility performing the examination be identified on the report and lay summary?

Answer: Yes. While mammography reports and lay summaries may go out under letterheads other than that of the certified facility, the name of the certified facility performing the mammography examination must also be identified on the report and lay summary.

Question: Must the radiologic technologist performing the mammogram be identified in the mammography report and lay summary?

Answer: No. While the radiologic technologist must be identified on the mammographic images, the technologist does not have to be identified in either the mammography report or lay summary.

21 CFR 900.12(c)(1)(iv)

[The report shall contain] Overall final assessment of findings, classified in one of the following categories:

- (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);*
- (B) "Benign:" Also a negative assessment;*
- (C) "Probably Benign:" Finding(s) has a high probability of being benign;*
- (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;*
- (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;*

21 CFR 900.12(c)(1)(v)

In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

21 CFR 900.12(c)(1)(vi)

Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

21 CFR 900.12(c)(2)

Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

- (i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.*
- (ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.*

Question: Does the lay summary have to be signed by the interpreting physician?

Answer: No. While the mammography report must be signed by the interpreting physician, the lay summary does not have to be signed.

Question: Does the lay summary have to have a final assessment category?

Answer: No. While the lay summary will be based on the medical report's final assessment category, the summary does not have to include a final assessment category.

Question: Do we have to provide lay summaries translated into different languages for our patients who cannot read English?

Answer: Facilities are required to provide lay summaries of their mammography reports to all their patients. The content of the lay summary is left to the facility so that the summary may be customized to adequately convey information to the patient. While facilities are not required under MQSA to provide summaries in different languages, those facilities with sizable non-English reading populations should make reasonable efforts to accommodate these patients through the provision of appropriate foreign language summaries.

Question: How should a facility handle a lay summary that is returned “undeliverable?”

Answer: The requirement to communicate results to the patient can be fulfilled by mailing the lay summary to the patient (at the patient’s last known address), even when the lay summary is returned to the facility and marked as “undeliverable.” While this will satisfy the MQSA requirement, the facility may still be responsible for further attempts at patient communication under their State requirements or Standards of Care. This is especially true where the results are “suspicious” or “highly suggestive of malignancy.”

Question: How is a facility required to deal with providing lay summaries to patients who, for whatever reason, cannot communicate?

Answer: The requirement to communicate results to the patient can be fulfilled by providing (e.g., mailing) the lay summary to the patient, even when the patient cannot communicate. In most of these cases, however, the facility will be aware of this condition at the time of the study and should identify a legally responsible party to whom to send the lay summary. While sending a lay summary to the patient (or a legally responsible party) constitutes official communication and will satisfy the MQSA requirement, the facility may still be responsible for further attempts at patient (or legally responsible party) communication under their State requirements or Standards of Care. This is especially true where the results are “suspicious” or “highly suggestive of malignancy.” Facilities should make reasonable accommodations to try to ensure that results are communicated to all patients or their legally responsible party.

Question: Must the radiologic technologist performing the mammogram be identified in the mammography report and lay summary?

Answer: No. While the radiologic technologist must be identified on the mammographic images, the technologist does not have to be identified in either the mammography report or lay summary.

Question: Must a lay summary be provided to the patient if the images from an examination are re-read by a physician not associated with the facility where the examination was originally performed and interpreted (e.g., if the patient or health care provider requests a second opinion from another facility)?

Answer: No, there is no requirement that a lay summary be provided to the patient when re-interpretations of images are done at a facility different from the facility that made the original interpretation. However, FDA strongly recommends that the second facility inform the patient requesting the second opinion of the results, especially when the second opinion differs from the initial results.

21 CFR 900.12(c)(3)

Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

Question: Our facility's mammography reports are accessible to our health care providers on computer. Because of this, we do not print out reports to send to the providers. Will providing the mammography reports through the use of computers (e.g., E-mail) be acceptable under the final regulations?

Answer: Computer reports are acceptable under the final regulations. However, facilities should be aware that the regulations require that mammography reports be provided to referring health care providers and to self-referred patients and also must be transferred, on the request of the patient or on her behalf, to other medical institutions or health care providers or to the patient herself. The facility may develop appropriate procedures for providing these reports. Facilities may use different means of communication for dealing with the specific situations described above. Where electronic means (e.g., E-mail) will successfully provide the reports to their required recipients, they may be used. However, where electronic means can't achieve this goal, hard copy (paper) reports must be provided.

Question: Must a mammography report be provided to the health care provider or self-referred patient if the images from an examination are re-read by a physician not associated with the facility where the examination was originally performed and interpreted (e.g., if the patient or health care provider requests a second opinion from another facility)?

Answer: No, there is no requirement that a mammography report be provided when re-interpretations of images are done at a facility different from the facility that made the original interpretation. However, FDA strongly recommends that the second facility inform the health care provider or self-referred patient requesting the second opinion of the results, especially when the second opinion differs from the initial results.

900.12(c)(5)

Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

- (i) Name of patient and an additional patient identifier.*
- (ii) Date of examination.*
- (iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with Sec. 900.3(b) or Sec. 900.4(a)(8) shall be used to identify view and laterality.*
- (iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.*
- (v) Technologist identification.*
- (vi) Cassette/screen identification.*
- (vii) Mammography unit identification, if there is more than one unit in the facility.*

Question: We have limited space in our film flasher and do not want to use “stick-on” labels. Can we abbreviate our facility name and address?

Answer: The intent of this regulation is to ensure that, in the event the films become separated from any other identifying materials, the originating mammography facility can be readily identified and the films can be returned or the facility contacted, if necessary. Abbreviations of the facility name, city, State and zip code (5 vs. 9 digit) are acceptable as long as the abbreviations clearly identify these items and are not ambiguous.

Quality Assurance - General

21 CFR 900.12(d)

Quality assurance--general. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

(1) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(i) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(ii) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

(A) Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

(B) Participate in the facility's medical outcomes audit program.

(iii) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys

and mammography equipment evaluations and providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this section.

(iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.

Question: Can a facility designate more than one lead interpreting physician at a time?

Answer: No. While a facility can change who is designated as the lead interpreting physician, there can be only one lead interpreting physician at any one time.

Question: Can a facility designate more than one quality control technologist at a time?

Answer: While the regulations allow a facility to designate more than one quality control technologist at a time, FDA recommends that this option be used sparingly. Having a single quality control technologist who has overall responsibility for the portions of the quality assurance program not assigned to the lead interpreting physician or medical physicist generally allows for better management of the system.

Question: Must the lead and audit physician(s) be listed as interpreting physician(s) at the facility?

Answer: Yes. The lead and audit physician(s) must be listed as interpreting physician(s) at the facility so that their qualifications can be evaluated at the time of the inspection. This does not require that the physician(s) actually interpret examinations at the facility.

Quality Assurance – Records

21 CFR 900.12(d)(2)

Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. The quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Question: How long do “Personnel Responsibilities”, “Technique Charts” and “Procedures for Safety and Protection of Patients & Personnel” records have to be maintained?

Answer: The purpose of the quality assurance records is to demonstrate that the quality assurance requirements are met. Records of “Personnel Responsibilities” (and employee qualifications to meet the assigned responsibilities), “Technique Charts” (and the other records on mammography technique and procedures), and “Procedures for Safety and Protection of Patients and Personnel”, change infrequently and irregularly. These records must be kept until the first inspection after each update and until any questions from that inspection have been resolved. Once this has been done, the updated record must be retained to show that the requirement continues to be met, however, the old record can be discarded, if the facility wishes.

In contrast to the quality assurance records, specific time periods have been established for retention of the quality control records, for which new information is collected on a required schedule.

Question: Is it acceptable for a technique chart to simply state that the facility is using the unit in its fully automatic mode (e.g., BACE, AOP, or similar modes) for all routine examinations?

Answer: Yes. However, if such a technique chart is used, the facility may not use the unit if the automatic mode listed on the technique chart fails. For this reason, FDA strongly recommends that the facility develop, and have available, a technique chart that includes manual techniques and/or other AEC modes. The technique chart could then be used as a guide for the radiologic technologist in the event that the fully automatic mode failed or was not suitable for use with a specific patient.

Quality Control (QC) Tests – General/Other Than Annual

Question: Under the final regulations, must facilities chart the data for quality control tests, such as processor sensitometry or phantom image evaluation?

Answer: No. While facilities are required to keep records for the required QC tests, facilities are not required to record the data on charts or graphs. However, we believe that charting/graphing of these test data provides a valuable tool for the facility to monitor trends associated with the data and to take corrective action prior to equipment performance exceeding regulatory action limits. The use of charts/graphs will also serve to expedite the inspection process resulting in significant savings in facility time and resources.

Question: How should facilities retain QA/QC records for equipment (film processors and/or mammographic units) that were in use for a period of time between the previous MQSA inspection and the current inspection, and have since been retired from use and replaced with new equipment?

Answer: The requirement for maintenance of QA/QC records for equipment currently being used is that these records must be maintained until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the requirements or until the test has been performed two additional times at the required frequency, whichever is longer. However, for film processors and/or mammographic units that are no longer at the facility, the records need only be kept for that equipment until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the requirements.

Question: Must the QC records indicate the actual numerical result of the QC test (e.g. compression, fixer retention) or just whether it passes or fails?

Answer: QC records must show the numerical results of those QC tests for which numbers are a natural by-product of the test. These numerical results will indicate whether the QC tests are within the required action or control limits. These numerical results must be provided in addition to the pass/ fail indication. However, for tests such as artifact evaluation, where no meaningful quantitative test results are produced, a pass/fail indication would be appropriate and sufficient.

21 CFR 900.12(e)(2)

Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

- (i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.*
- (ii) The optical density of the film at the center of the phantom image shall not change by more than <plus-minus> 0.20 from the established operating level.*
- (iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).*
- (iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than <plus-minus> 0.05 from the established operating level.*

Question: If a weekly QC test is performed every week but not every 7 days, can the facility be cited?

Answer: No. Since the regulations do not specify that the weekly test be performed on the same day every week (i.e., every 7 days), the facility can not be cited if it performs the weekly test every week but on different days in different weeks.

Question: When performing the weekly phantom QC test, should we use film from the box currently being used to produce clinical exams or film from the box used for quality control purposes?

Answer: It is recommended that the phantom image evaluation test be performed using films from the box currently being used to produce clinical mammograms. If dedicated boxes of QC films are used for the phantom tests, the chance of detecting problems with the clinically used film is sacrificed.

FDA realizes that, due to differences in emulsion batches, a phantom image test with films from a new box may show variance in optical density and density difference greater than the allowed limits (when measured against the operating level established with films from the previous box). In such a case, facilities are advised to first check the whole imaging chain including the processor performance (facilities may wish to contact their medical physicist for help with this process). If no problems are detected, the facility may assume the change is due to different film emulsions. They may then adjust their typical clinical technique factors to meet the phantom optical density requirements.

Question: When evaluating the phantom QC test, must the technologist and the physicist adjust the phantom scoring for artifacts?

Answer: A facility must follow the phantom image scoring methodology established by its accreditation body.

Question: We perform our weekly phantom images using the AEC mode rather than the Full-Auto mode that we typically use for patients. Is this acceptable toward meeting the requirement?

Answer: No. If the facility clinically uses the Full-Auto mode for its standard breast patients, the weekly phantom images must be obtained using that mode. FDA requires the weekly phantom image be produced using the same clinical conditions that are used for its patients with the standard breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition). Prior to performing mammography on patients, the phantom image must achieve at least the minimum phantom score established by the accreditation body and must be within the action limits established for the 3 optical density requirements.

Question: When performing the weekly phantom image test must we monitor kVp and/or mAs?

Answer: No. The only requirements on the weekly phantom image test are that the phantom image achieve at least the minimum phantom score established by the accreditation body and must be within the action limits established for the 3 optical density requirements. FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate an equipment problem and should be further evaluated.

Mobile facilities should be aware of the following if they are monitoring mAs as part of their post-move-pre-exam testing. Performing the post-move-pre-exam test in the Full-Auto mode may be inappropriate (due to the variability of kVp and mAs as previously mentioned). In such cases, the facility should use the AEC mode to perform the post-move-pre-exam test, even if they use the Full-Auto mode for their patients with the standard breast. Note: The weekly phantom QC test must be performed using the same clinical conditions that the facility uses for its patients with the standard breast.

Question: If the OD for the weekly phantom test falls below 1.20, must the unit be recalibrated or can we adjust the density setting to obtain a 1.20 OD?

Answer: If the OD at the center of the phantom image falls below the required minimum of 1.20 OD, the facility should take the following steps:

1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images.
2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications.
3. Check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images (assuming that the facility has been tracking mAs and has been using the same kVp and film emulsion/screen combination). If the mAs has changed by more than 15%, the medical physicist should be called to check the entire imaging chain, including the mammography unit.
4. Adjust the density control setting (if no problems are found in steps 2 and 3) to obtain a density of at least 1.20 OD at the center of the phantom image.
5. Adjust the density control settings used clinically to be consistent with the changes in step 4.

If the density again falls below 1.20 OD the next time the phantom image is performed (using the film from the same box and the same density and processor settings), the facility should consult with its physicist and check the entire imaging chain before performing mammograms.

Question: If the OD for the weekly phantom test changes by more than ± 0.20 from the established operating level, must the unit be recalibrated or can we adjust the density setting to bring the OD within the action limits of the operating level?

Answer: If the OD changes by more than ± 0.20 from the established operating level, the facility should take the following steps:

1. Ensure that the phantom is exposed using typical clinical conditions and that the position of the phantom and, where appropriate, the position of the AEC detector have not changed from that used for prior images.
2. Reevaluate the daily processor performance and make sure the processor is properly optimized according to the film manufacturer's specifications.
3. Check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images (assuming that the facility has been tracking mAs and has been using the same kVp and film emulsion/screen combination). If the mAs has changed by more than 15%, the medical physicist should be called to check the entire imaging chain, including the mammography unit.
4. Adjust the density control setting (if no problems are found in steps 2 and 3) to obtain a density within ± 0.20 of the established operating level.
5. Adjust the density control settings used clinically to be consistent with the changes in step 4.

If the density again changes by more than ± 0.20 from the established operating level (using the film from the same box and the same density and processor settings), the facility should consult with its physicist and check the entire imaging chain before performing mammograms.

Question: Must the weekly phantom test be performed for all image receptor sizes?

Answer: No, facilities are not required to perform phantom image evaluation for all image receptor sizes. Phantom image quality should not be significantly affected by receptor size. Because all currently approved phantoms simulate a standard breast, FDA recommends that the small image receptor size be used for phantom image evaluation.

Question: Must the interpreting physician evaluate the weekly phantom QC test?

Answer: No, the regulations do not require that the interpreting physician evaluate the weekly phantom QC test. However, the interpreting physicians may perform or evaluate the weekly phantom QC test, if the facility so chooses.

21 CFR 900.12(e)(4)

Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

- (i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.*
- (ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.*

Question: Must the screen-film contact and uniformity of screen speed tests be performed on new cassettes prior to clinical use and must the medical physicist perform the tests?

Answer: The screen-film contact and uniformity of screen speed tests must be performed on new cassettes prior to clinical use. Because the screen-film contact test is a semi-annual QC test, the QC technologist may perform this test. The uniformity of screen speed test is part of the annual physicist's survey and, in that context, must be performed by the medical physicist. However, in the context of cassettes being added during the course of the year (between annual physics surveys), the QC technologist (or someone with adequate training designated by the QC technologist) can perform this test in consultation with the medical physicist. The facility is reminded, however, that if the newly acquired cassette(s) are used to image the standard breast and are of a significantly slower speed from the existing group of cassettes, a mean glandular dose measurement must be performed for the new group of cassette(s). In such a case, the medical physicist must perform this dose measurement test before this group of cassettes is used on patients.

(iii) Compression device performance.

- (A)** *A compression force of at least 111 newtons (25 pounds) shall be provided.*
- (B)** *Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).*

Question: What compression device performance requirements are in effect prior to October 28, 2002?

Answer: Until October 28, 2002, the only requirements regarding compression device performance are that it be provided and that it be capable of generating at least 25 pounds of pressure. The pressure can be generated using manual or power drive or a combination of both.

Question: Several mammography units have initial compression devices that generate more than 45 pounds of pressure. Will they have to be replaced or modified after October 28, 2002?

Answer: Yes, these units will have to be replaced or modified to meet the regulations. The regulations require that effective October 28, 2002, the initial power drive compression must not exceed 45 pounds (200 newtons). The purpose of this requirement is to help prevent patient injury due to the inappropriate use of excessive compression force. Units providing a maximum initial compression force of more than 45 pounds (200 newtons) will be non-compliant after October 28, 2002. Compression forces greater than 45 pounds (200 newtons) are allowed in the fine adjustment mode.

QC Tests - Annual

21 CFR 900.12(e)(5)

Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

- (i) *Automatic exposure control performance.*
 - (A) *The AEC shall be capable of maintaining film optical density within <plus-minus> 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within <plus-minus> 0.30 of the average under phototimed conditions can be produced.*
 - (B) *After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within <plus-minus> 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.*
 - (C) *The optical density of the film in the center of the phantom image shall not be less than 1.20.*

Question: Do units with multiple AEC detectors have to have each detector tested individually?

Answer: Where a mammography unit has multiple AEC detectors designed to function independently, each detector must be tested separately (e.g., different AEC detectors for the different size cassette holders or more than one independently selectable AEC detector in a single cassette holder). Where a mammography unit has multiple AEC detectors designed to function as a single unit, the AEC detector unit must be tested. For example, a single detector that can be moved to different positions needs to have the detector tested at only one of those positions. A system with three fixed detectors, each of which can be selected individually, needs to have all three detectors tested. A large field detector that automatically selects its active area needs to be tested only as a single detector.

(ii) *Kilovoltage peak (kVp) accuracy and reproducibility.*

(A) *The kVp shall be accurate within <plus-minus> 5 percent of the indicated or selected kVp at:*

- (1)** *The lowest clinical kVp that can be measured by a kVp test device;*
- (2)** *The most commonly used clinical kVp;*
- (3)** *The highest available clinical kVp, and*

(B) *At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.*

Question: Does this regulation require that kVp be within 5% agreement with an absolute standard or within 5% agreement with the field measuring instrument?

Answer: The final regulations require that the kVp be accurate within $\pm 5\%$ of the indicated or selected kVp. The agency realizes that many non-invasive kVp measurement meters may not provide that level of absolute accuracy when compared to a national standard. The intent of the regulation is that the indicated or selected kVp be within $\pm 5\%$ of the value measured by the meter used.

(viii) *Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.*

Question: Must the screen-film contact and uniformity of screen speed tests be performed on new cassettes prior to clinical use and must the medical physicist perform the tests?

Answer: The screen-film contact and uniformity of screen speed tests must be performed on new cassettes prior to clinical use. Because the screen-film contact test is a semi-annual QC test, the QC technologist may perform this test. The uniformity of screen speed test is part of the annual physicist's survey and, in that context, must be performed by the medical physicist. However, in the context of cassettes being added during the course of the year (between annual physics surveys), the QC technologist (or someone with adequate training designated by the QC technologist) can perform this test in consultation with the medical physicist. The facility is reminded, however, that if the newly acquired cassette(s) are used to image the standard breast and are of a significantly slower speed from the existing group of cassettes, a mean glandular dose measurement must be performed for the new group of cassette(s). In such a case, the medical physicist must perform this dose measurement test before this group of cassettes is used on patients.

(x) *Radiation output.*

(A) *The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800*

mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

- (B)** *The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.*

Question: Radiation output is to be measured over a 3 second period. Can exposures of less than 3 seconds meet the requirement as long as the total output meets the requirement?

Answer: Yes. The intent of this regulation is to ensure that all mammography units have the capability of achieving the proper film exposure level without excessively long exposure times. Units that are capable of producing at least 13.5 mGy air kerma (1539 mR) within a 3 second period or less meet the requirement. After October 28, 2002, units must be capable of producing at least 21 mGy air kerma (2400 mR) within a 3 second period or less.

(xi) *Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:*

- (A)** *An override capability to allow maintenance of compression;*
- (B)** *A continuous display of the override status; and*
- (C)** *A manual emergency compression release that can be activated in the event of power or automatic release failure.*

Question: We have a DMR unit in which the automatic decompression override status is displayed only under certain conditions, does this still meet the requirement to be continuously displayed?

Answer: Yes. If the “certain conditions” referred to are:

1. The automatic decompression override status displays only when compression is applied, or
2. If there are other messages displayed in addition to the override status, the display of the override status will cycle with the other messages, thus override status will be interrupted briefly while the other messages are displayed (this feature is also characteristic of some other models of GE mammographic units).

We have determined that these conditions satisfy the intent of the requirement, which is that there must be means to alert the operator to the status of the automatic decompression override so that he or she may change that status, if he or she wishes, before producing the mammographic images.

Question: Our unit’s automatic decompression mechanism has been deactivated and can’t be reactivated by anyone at the facility. Does its status still have to be continuously displayed?

Answer: No. If that mechanism has been disabled and can’t be reactivated by the operators then, in our view, the unit does not have an automatic decompression mechanism. Because the requirement for a continuous display, like all the other requirements in this section, applies only to units with an automatic decompression mechanism, your unit does not have to have such a display. Should the

automatic decompression mechanism be reactivated in the future, then your unit would have to meet all applicable requirements, including the requirement for a continuous display of the override status.

FDA recommends that the fact that the automatic decompression mechanism has been disabled, be indicated by a label on the control panel so that all operators, old and new, are fully aware of this.

Question: Must all mammography units have an emergency compression release?

Answer: The emergency release is only required for those systems with automatic decompression (which may fail to operate in the event of a power failure). However, FDA recommends that all systems provide for the emergency release of patients.

Question: The regulations state that while in automatic decompression override status, mammography equipment must provide "maintenance of compression" after completion of an exposure or in case of a power interruption. What degree of compression and for how long must it be maintained?

Answer: The intent of this requirement is that systems in override status allow the continuation of compression so that it is not released in a manner likely to cause patient injury. The facility should evaluate system use in their clinical setting. Those systems used for both invasive and non-invasive procedures provide the greatest potential for injury. In this context, the degree of compression and the time for which it is maintained should be assessed with regard to the potential for patient injury.

Medical Physicist's Annual Survey

21 CFR 900.12(e)(9)

Surveys.

- (i) *At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.*
- (ii) *The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*
- (iii) *The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.*
- (iv) *The survey report shall be sent to the facility within 30 days of the date of the survey.*
- (v) *The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.*

Question: Under the interim regulations, FDA allowed some flexibility with respect to scheduling physics surveys. Will this continue under the final regulations?

Answer: Yes. While the medical physics survey must be performed annually, FDA realizes that surveys cannot usually be scheduled exactly on the anniversary date of the previous survey. Therefore an occasional period of up to 14 months between surveys is acceptable. Facilities may choose, however, to have the physics surveys performed at higher frequencies (shorter intervals) during any annual cycle.

Question: Will physics surveys performed before 4/28/99 but inspected after 4/28/99 be evaluated against the standards of the final regulations?

Answer: No. Physics surveys performed under the interim regulations (before April 28, 1999) will be evaluated against the standards of the interim regulations even if the facility is inspected after April 28, 1999.

Question: When conducted for the annual survey, must all the tests be performed by, or under the direct supervision of, a medical physicist?

Answer: Yes. All testing conducted to satisfy the annual physicist survey requirements of 900.12(e)(9) must be performed by, or under the direct supervision of, an MQSA qualified medical physicist.

21 CFR 900.12(e)(10)

Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

Question: Must a currently certified facility or a facility undergoing certification for the first time have the final written report of the equipment evaluation before clinically using a newly added or modified unit?

Answer: No, however, the currently certified facility or a facility undergoing certification for the first time must have, at a minimum, a written document of the test results, provided by the medical physicist, before any clinical use of the new or modified equipment. This initial documentation can simply be a list of all applicable tests performed on the equipment with an indication that the equipment passed all the tests. Mammography equipment evaluations must be performed by qualified medical physicists and must determine whether the new or modified equipment meets the requirements of applicable standards stated in sections 900.12(b) and (e) of the final regulations.

Mammography Medical Outcomes Audit

21 CFR 900.12 (f)(1)

General requirements.

Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently became known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

Question: An interpreting physician has left our facility since completing our last medical audit. Does he/she still have to be included in this year's medical audit?

Answer: Yes. All interpreting physicians must be included in the audit. While the number of cases included in the audit for such physicians may be low, this information can give the facility an idea of whether the physician is consistent with the rest of the interpreting physicians at the facility. Because the physician is no longer at the facility, there is no requirement that the facility inform this physician of his/her audit results. For self-assessment purposes, it is recommended that the physician try to obtain his/her audit results.

Question: We used a locum tenens interpreting physician during the year, but only for a short time. Does he/she still have to be included in our medical audit?

Answer: Yes. All interpreting physicians must be included in the audit. While the number of cases included in the audit for such a physician may be low, this information can give the facility an idea of whether the locum tenens is consistent with the rest of the interpreting physicians at the facility. Because the physician is no longer at the facility, there is no requirement that the facility inform this physician of his/her audit results. For self-assessment purposes, it is recommended that the locum tenens physician try to obtain his/her audit results from all the facilities where mammography services were provided.

Question: How should "false negatives" be included in the medical audit?

Answer: Facilities must include in their audit, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility. The manner in which this information is included in the audit is left up to the facility. For example, whether to include such information in the analysis for the year in which the mammogram was originally performed or for the year when the cancer was discovered is left up to the facility. The facility's guiding principle should be to present the information in the manner most useful to the facility. Because of the rarity of "false negatives," FDA also recommends that facilities periodically review all such cases to determine if there are any patterns to their occurrence that may only be evident by looking at more than a single year's analysis.

Question: If a facility becomes aware of breast cancer in a patient whose mammogram was performed more than one year ago, do they still have to review that mammogram and include it in the audit?

Answer: Yes. Because the growth rate of breast cancer can be quite variable, facilities are required to perform such reviews on all cases where they still have the mammogram. Since facilities are required to maintain the most recent mammogram for ten years (unless the films have been transferred), facilities could be reviewing films as old as ten years.

21 CFR 900.12 (f)(3)

Audit interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and for notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the audit interpreting physician shall also be responsible for documenting the nature of the followup.

Question: Must the lead and audit physician(s) be listed as interpreting physician(s) at the facility?

Answer: Yes. The lead and audit physician(s) must be listed as interpreting physician(s) at the facility so that their qualifications can be evaluated at the time of the inspection. This does not require that the physician actually interpret examinations at the facility.

Question: Can a facility designate more than one audit interpreting physician at a time?

Answer: While the regulations allow a facility to designate more than one audit interpreting physician at a time, FDA recommends that this option be used sparingly. Having a single audit interpreting physician who has overall responsibility for the medical audit generally allows for better management of the system.

Consumer Complaint Mechanism

21 CFR 900.12 (h)

Consumer complaint mechanism.

Each facility shall:

- (1) Establish a written and documented system for collecting and resolving consumer complaints;*
- (2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;*
- (3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;*
- (4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.*

Question: Does the complaint mechanism have to be posted?

Answer: No. The final regulations do not require facilities to post a sign describing how consumers can file complaints. The MQSA certificate includes the name and address of the facility's accreditation body, and filing a complaint with the accreditation body is the next step for consumers registering a complaint. The facility is required to post their certificate prominently within the view of patients.

The final regulations also require the facility to give consumers with serious unresolved complaints directions for filing such complaints with the facility's accreditation body.

While not required, FDA encourages facilities to post a sign informing their patients of the presence of its complaint mechanism. Facilities can use messages such as, "We care about our patients. If you have comments, compliments, and/or concerns, please direct them to (the name of the person at the facility who is responsible for complaints)."

Additional suggestions for making patients aware of the complaint mechanism include: providing information about the complaint mechanism on the patient information sheet filled out before the exam, and requesting that patients complete a comment card following the mammography exam. FDA also encourages the facility to train its staff to be receptive to patient concerns so that the patient will feel comfortable in expressing those concerns.